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/Lynne M. Milliot/
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of inventor(s): **Michael G. Kahn**	Group Art Unit: **3626**
Application No. **09/584,936**	Examiner: **Lena Najarian**
Confirmation No. **5001**	
Filing Date: **31 May 2000**	
Title: **Clinical Trials Management System and Method**	**CUSTOMER NO. 22470**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT/RESPONSE UNDER 37 C.F.R. §1.116

Sir:

This RESPONSE F is in reply to the final Office Action mailed 23 February 2007. A NOTICE OF APPEAL is submitted herewith.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 22 of this paper.

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Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (previously presented) At least one computer readable medium collectively carrying a machine readable database identifying:

first patient eligibility criteria for a first clinical trial protocol; and

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow tasks to be performed for a particular patient,

wherein the post-enrollment workflow tasks include at least one element of the group consisting of a post-enrollment instruction to have a specified test performed on the patient, and a post-enrollment instruction to have a specified CRF completed for the patient.

2. (original) A medium according to claim 1, wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol.

3. (original) A medium according to claim 1, wherein said database identifies a term by reference to a controlled medical terminology database.

4. (previously presented) A medium according to claim 1, wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified CRF completed for the patient.

5. (previously presented) A medium according to claim 4, wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient.

6. (canceled)

7. (withdrawn) A method according to claim 4, wherein said data management tasks include an instruction for a clinician to obtain informed consent of a patient.

8. (previously presented) A medium according to claim 1, wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before an instruction to obtain informed consent.

9. (previously presented) A medium according to claim 8, wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

10. (previously presented) A medium according to claim 4, wherein said first plurality of workflow tasks further include an instruction to enroll a patient into a clinical trial.

11. (previously presented) A medium according to claim 1, wherein said first plurality of workflow tasks include an instruction to enroll a patient into a clinical trial.

12. (withdrawn) At least one computer readable medium collectively carrying a machine readable database identifying:

a plurality of patient management tasks for a first clinical trial protocol; and

a plurality of data management tasks for said first clinical trial protocol.

13. (withdrawn) A medium according to claim 12, wherein said database further identifies patient eligibility criteria applicable to said first clinical trial protocol.

14. (withdrawn) A medium according to claim 12, wherein said database identifies a term by reference to a controlled medical terminology database.

15. (withdrawn) A method according to claim 12, wherein said plurality of patient management tasks includes post-enrollment patient management tasks.

16. (withdrawn) method according to claim 12, wherein said plurality of data management tasks includes an instruction for a clinician to complete a specified form.

17. (withdrawn) A method according to claim 12, wherein said plurality of data management tasks includes an instruction for a clinician to obtain informed consent of a patient.

18. (withdrawn) A method according to claim 17, wherein said plurality of patient management tasks includes an instruction to obtain specified patient medical information before said instruction to obtain informed consent.

19. (withdrawn) A method according to claim 18, wherein said plurality of patient management tasks further includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

20. (withdrawn) A method according to claim 17, wherein said plurality of data management tasks further includes an instruction to enroll a patient into a clinical trial.

21. (withdrawn) A method according to claim 12, wherein said plurality of data management tasks includes an instruction to enroll a patient into a clinical trial.

22. (withdrawn) A clinical trials method, comprising the steps of:

storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks; and

providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

23. (withdrawn) A method according to claim 22, further comprising the step of authorizing each of said clinical sites to perform trials of the clinical trial protocols to which the site is provided access.

24. (withdrawn) A method according to claim 22, wherein said step of providing access comprises the step of downloading the database for a particular one of said protocols to a particular one of said clinical sites.

25. (withdrawn) A method according to claim 22, wherein said step of providing access comprises the step of allowing a particular one of said clinical sites remote access to the database for a particular one of said protocols.

26. (withdrawn) A method according to claim 22, further comprising the step of downloading at least a subset of said databases to a particular one of said clinical sites,

wherein said step of providing access comprises the step of allowing said particular clinical site to access one of the databases downloaded.

27. (withdrawn) A method according to claim 22, further comprising the step of receiving said databases from a plurality of different protocol designers.

28. (withdrawn) A method according to claim 22, wherein each of said databases identifies:

patient eligibility criteria for the respective clinical trial protocol; and

a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks.

29. (withdrawn) A method according to claim 28, wherein each of said databases further identifies preliminary patient eligibility criteria applicable to the respective clinical trial protocol.

30. (withdrawn) A method according to claim 22, wherein each of said databases identifies:

a plurality of patient management tasks for the respective clinical trial protocol; and

a plurality of data management tasks for the respective clinical trial protocol.

31.-35. (canceled)

36. (withdrawn) A medium according to claim 31, wherein each of said protocol databases identifies:

a plurality of patient management tasks for the respective clinical trial protocol; and a plurality of data management tasks for the respective clinical trial protocol.

37-44. (canceled)

45. (withdrawn) A method for designing clinical trial protocols, comprising the steps of:

defining an initial group of first eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol; and

simulating patient accrual in dependence upon said initial group of first eligibility criteria.

46. (withdrawn) A method according to claim 45, further comprising the step of revising said initial group of first eligibility criteria in dependence upon said step of simulating.

47. (withdrawn) A method according to claim 46, further comprising the step of iteratively repeating said steps of simulating and revising, until the step of simulating predicts an acceptable patient accrual rate.

48. (withdrawn) A method according to claim 45, wherein said step of defining an initial group of first eligibility criteria comprises the steps of:

selecting a first list of patient attributes from a plurality of pre-existing lists of patient attributes; and

establishing each of the first eligibility criteria in said initial group by assigning an initial condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria.

49. (withdrawn) A method according to claim 45, further comprising the steps of:

selecting, from a plurality of pre-existing lists of patient attributes, a first one of said lists for use in defining preliminary eligibility criteria for said particular clinical trial protocol; and

establishing each of said preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria,

and wherein said first eligibility criteria are further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

50. (withdrawn) A method according to claim 45, wherein said first eligibility criteria include both preliminary eligibility criteria and further eligibility criteria, said further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

51. (withdrawn) A method for designing clinical trial protocols, comprising the steps of:

defining an initial group of first eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol; and

polling clinical sites for expected patient accrual in dependence upon said initial group of first eligibility criteria.

52. (withdrawn) A method according to claim 51, further comprising the step of revising said initial group of first eligibility criteria in dependence upon said step of polling.

53. (withdrawn) A method according to claim 52, further comprising the step of iteratively repeating said steps of polling and revising, until the step of polling predicts an acceptable total patient accrual rate.

54. (withdrawn) A method according to claim 51, wherein said step of defining an initial group of first eligibility criteria comprises the steps of:

selecting a first list of patient attributes from a plurality of pre-existing lists of patient attributes; and

establishing each of the first eligibility criteria in said initial group by assigning an initial condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria.

55. (withdrawn) method according to claim 51, further comprising the steps of:

selecting, from a plurality of pre-existing lists of patient attributes, a first one of said lists for use in defining preliminary eligibility criteria for said particular clinical trial protocol; and

establishing each of said preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria,

and wherein said first eligibility criteria are further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

56. (withdrawn) A method according to claim 51, wherein said first eligibility criteria include both preliminary eligibility criteria and further eligibility criteria, said further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

57. (withdrawn) A method for clinical trials, comprising the steps of:

obtaining a first subset of patient information items about each of a plurality of patients;

comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial;

recording said first subset of patient information items about each of said patients to a database; and subsequently

comparing the first subset of patient information items about each of said patients from said database against second eligibility criteria for a second clinical trial for a purpose of determining patient eligibility for said second clinical trial.

58. (withdrawn) A method according to claim 57, further comprising the steps of:

obtaining a second subset of patient information items about each of at least a subset of said plurality of patients, after said step of comparing the first subset of patient information items about each of said patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

comparing the second subset of patient information items about each of said subset of patients against second eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial.

59. (withdrawn) A method according to claim 58, further comprising the step of recording said second subset of patient information items about each of said subset of patients to said database.

60. (withdrawn) A method according to claim 59, further comprising the step of comparing the second subset of patient information items about each of said subset of patients from said database against eligibility criteria for said second clinical trial for a purpose of determining patient eligibility for said second clinical trial.

61. (withdrawn) A method according to claim 57, further comprising the steps of:

obtaining a preliminary subset of information items about each of a group of patients including said plurality of patients; and

comparing the preliminary subset of patient information items about each patient in said group of patients against preliminary eligibility criteria for said first clinical trial prior to said step of comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria.

62. (withdrawn) A method according to claim 61, further comprising the step of recording said preliminary subset of patient information items about each patient in said group of patients to said database.

63. (withdrawn) A method according to claim 61, further comprising the step of selecting said plurality of patients in dependence upon said step of comparing the preliminary subset of patient information items.

64. (withdrawn) A method according to claim 57, wherein said step of recording said first subset of information items about each of said patients to a database includes the step of recording in said database an identity of the patient to which each of said information items relates.

65. (withdrawn) A method according to claim 57, wherein at least one of said first eligibility criteria is defined according to a predefined controlled medical terminology.

66. (withdrawn) A method for designing clinical trial protocols, comprising the steps of:

selecting, from a plurality of pre-existing lists of patient attributes, a first one of said lists for use in defining preliminary eligibility criteria for a first clinical trial protocol;

establishing each of said preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria; and

defining further eligibility criteria for the first clinical trial protocol, said further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said first protocol as determined by said preliminary eligibility criteria.

67. (withdrawn) A method according to claim 66, wherein said step of assigning a condition to a corresponding one of the attributes in said first list comprises the step of selecting a value for the attribute from a predetermined set of available values for the attribute.

68. (withdrawn) A method according to claim 66, wherein said step of assigning a condition to a corresponding one of the attributes in said first list comprises the step of selecting a plurality of acceptable values for the attribute from a predetermined set of available values for the attribute.

69. (withdrawn) A method according to claim 66, wherein said preliminary eligibility criteria includes a criterion corresponding to each of the attributes in said first list.

70. (withdrawn) A method according to claim 66, wherein said preliminary eligibility criteria includes at least one inclusion criterion and at least one exclusion criterion.

71. (withdrawn) A method according to claim 66, further comprising the steps of:

establishing each of a plurality of preliminary eligibility criteria for a second clinical trial protocol by assigning a condition to a corresponding one of the attributes in said first list; and

defining second further eligibility criteria for the second clinical trial protocol, said second further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said second protocol as determined by said second preliminary eligibility criteria.

72. (withdrawn) A method according to claim 66, comprising the steps of:

selecting, from said plurality of pre-existing lists of patient attributes, a second one of said lists for use in defining second preliminary eligibility criteria for a second clinical trial protocol;

establishing each of the criteria in said second preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said second list; and

defining second further eligibility criteria for the second clinical trial protocol, said second further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said second protocol as determined by said second preliminary eligibility criteria.

73. (withdrawn) A method according to claim 66, further comprising the step of identifying said further eligibility criteria for the first clinical trial protocol in a first machine-readable protocol definition database in association with said first clinical trial protocol.

74. (withdrawn) A method according to claim 66, wherein said step of defining further eligibility criteria comprises the step of selecting a term from a predefined controlled medical terminology.

75. (withdrawn) A method for clinical trials, comprising the steps of:

at a first clinical site, obtaining a first subset of patient information items about each of a plurality of patients;

comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

transmitting said first subset of patient information items about each of said patients to a central database in conjunction with an identification of said first clinical site.

76. (withdrawn) A method according to claim 75, further comprising the steps of:

obtaining a second subset of patient information items about each of at least a subset of said plurality of patients, after said step of comparing the first subset of patient information items

about each of said patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

comparing the second subset of patient information items about each of said subset of patients against second eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial.

77. (withdrawn) A method according to claim 76, further comprising the step of transmitting said second subset of patient information items about each of said subset of patients to said central database.

78. (withdrawn) A method according to claim 75, further comprising the steps of:

obtaining a preliminary subset of information items about each of a group of patients including said plurality of patients; and

comparing the preliminary subset of patient information items about each patient in said group of patients against preliminary eligibility criteria for said first clinical trial prior to said step of comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria.

79. (withdrawn) A method according to claim 78, further comprising the step of transmitting said preliminary subset of patient information items about each patient in said group of patients to said central database.

80. (withdrawn) A method according to claim 78, further comprising the step of selecting said plurality of patients in dependence upon said step of comparing the preliminary subset of patient information items.

81. (withdrawn) A method according to claim 75, wherein said step of transmitting said first subset of patient information items about each of said patients to a central database in conjunction with an identification of said first clinical site consists of the step of transmitting said first subset of patient information items about each of said patients in patient-anonymized form to said central database in conjunction with an identification of said first clinical site.

82. (withdrawn) A method according to claim 75, wherein at least one of said first eligibility criteria is defined according to a predefined controlled medical terminology.

83. (withdrawn) A method for clinical trials, comprising the steps of:

receiving from a first clinical site a first subset of patient information items about each of a first plurality of patients, the first subset of patient information items having been compared against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

recording said first subset of patient information items in a central database.

84. (withdrawn) A method according to claim 83, further comprising the steps of:

receiving from said first clinical site a second subset of patient information items about each of at least a subset of said first plurality of patients, the second subset of patient information items about each of said subset of patients having been compared against second eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

recording said second subset of patient information items in said central database.

85. (withdrawn) A method according to claim 83, further comprising the steps of:

receiving from said first clinical site a preliminary subset of information items about each of a group of patients including said first plurality of patients, the preliminary subset of patient

information items about each patient in said group of patients having been compared against preliminary eligibility criteria for said first clinical trial; and

recording said preliminary subset of patient information items in said central database.

86. (withdrawn) A method according to claim 85, wherein said first plurality of patients was selected in dependence upon said preliminary subset of patient information items.

87. (withdrawn) A method according to claim 83, wherein said step of recording said first subset of patient information items in a central database includes the step of recording said first subset of patient information items in said central database in correspondence with an identity of said first clinical site.

88. (withdrawn) A method according to claim 83, further comprising the steps of:

receiving from a second clinical site, a second subset of patient information items about each of a second plurality of patients, the second subset of patient information items having been compared against said first eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

recording said second subset of patient information items in said central database.

89. (withdrawn) A method according to claim 88,

wherein said step of recording said first subset of patient information items in a central database includes the step of recording said first subset of patient information items in said central database in correspondence with an identity of said first clinical site

and wherein said step of recording said second subset of patient information items in said central database includes the step of recording said second subset of patient information items in said central database in correspondence with an identity of said second clinical site.

90. (withdrawn) A method according to claim 89, further comprising the step of querying said central database to simulate clinical site-specific patient accrual in dependence upon eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol.

91. (withdrawn) A method according to claim 90, wherein said particular clinical trial protocol is different from said first clinical trial protocol.

92. (withdrawn) A method according to claim 88, further comprising the steps of:

receiving from a clinical site, a third subset of patient information items about each of a third plurality of patients, the third subset of patient information items having been compared against said first eligibility criteria for a second clinical trial for a purpose of determining patient eligibility for said second clinical trial; and

recording said third subset of patient information items in said central database.

93. (withdrawn) A method according to claim 92,

wherein said step of recording said first subset of patient information items in a central database includes the step of recording said first subset of patient information items in said central database in correspondence with an identity of said first clinical site,

wherein said step of recording said second subset of patient information items in said central database includes the step of recording said second subset of patient information items in said central database in correspondence with an identity of said second clinical site,

and wherein said step of recording said third subset of patient information items in a central database includes the step of recording said third subset of patient information items in said central database in correspondence with an identity of the clinical site from which said third subset of patient information was received.

94. (withdrawn) A method according to claim 93, further comprising the step of querying said central database to simulate clinical site-specific patient accrual in dependence upon eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol.

95. (withdrawn) A method according to claim 94, wherein said particular clinical trial protocol is different from both said first and second clinical trial protocols.

96. (withdrawn) A method according to claim 83, wherein at least one of said first eligibility criteria is defined according to a predefined controlled medical terminology.

97. (withdrawn) A clinical trials method, comprising the steps of:

managing progress of a first plurality of patients in a first clinical trial according to a first predefined workflow graph formed as part of a first clinical trial protocol;

recording the progress of each of the patients in said first plurality of patients through said first workflow graph; and

transmitting the recorded progress of each of the patients in said first plurality of patients to a central database.

98. (withdrawn) A method according to claim 97, further comprising the steps of:

managing progress of a second plurality of patients in a second clinical trial according to a second predefined workflow graph formed as part of a second clinical trial protocol different from said first clinical trial protocol;

recording the progress of each of the patients in said second plurality of patients through said second workflow graph; and

transmitting the recorded progress of each of the patients in said second plurality of patients to said central database.

99. (withdrawn) A method according to claim 97, wherein said first workflow graph connects a first plurality of workflow tasks,

and wherein said step of transmitting the recorded progress of each of the patients in said first plurality of patients to a central database comprises the step of transmitting to said central database an indication of which of workflow tasks have been performed on each of the patients in said first plurality of patients.

100. (withdrawn) A method according to claim 99, wherein said step of transmitting the recorded progress of each of the patients in said first plurality of patients to a central database further comprises the step of transmitting to said central database patient medical status information collected from observation of each of the patients in said first plurality of patients.

101. (withdrawn) A method according to claim 97, wherein said step of transmitting the recorded progress of each of the patients in said first plurality of patients to a central database comprises the step of transmitting to said central database patient medical status information collected from observation of each of the patients in said first plurality of patients.

102. (withdrawn) A method according to claim 101, wherein said patient medical status information includes at least one information item defined according to a predefined controlled medical terminology,

receiving from each of said sites information items about each of a respective plurality of patients, each of said information items being relevant to one or more of said patient eligibility criteria; and

storing said information items in a database.

103. (withdrawn) A clinical trials method, comprising the steps of:

receiving from a first clinical site first notifications of progress of each of a first plurality of patients through a first predefined workflow graph formed as part of a first clinical trial and recording said first notifications in a database; and

receiving from said first clinical site second notifications of progress of each of a second plurality of patients through a second predefined workflow graph formed as part of a second clinical trial and recording said second notifications in said database.

104. (withdrawn) A method according to claim 103, wherein said first workflow graph connects a first plurality of workflow tasks,

and wherein said first notifications of progress of each of a first plurality of patients through a first predefined workflow graph include indications of which of workflow tasks have been performed on each of the patients in said first plurality of patients.

105. (withdrawn) A method according to claim 104, wherein said first notifications of progress further include patient medical status information collected from observation of patients in said first plurality of patients.

106. (withdrawn) A method according to claim 105, wherein said patient medical status information includes at least one information item defined according to a predefined controlled medical terminology.

107. (withdrawn) A method according to claim 103, further comprising the steps of:

receiving from a second clinical site third notifications of progress of each of a third plurality of patients through said first predefined workflow graph formed as part of said first clinical trial and recording said third notifications in said database.

108. (withdrawn) A method according to claim 107, further comprising the step of evaluating the progress notifications received from at least said first and second clinical sites for a purpose of developing a metric comparing relative clinical trial performance of at least said first and second sites.

109. (withdrawn) A method according to claim 103, further comprising the step of evaluating the progress notifications received from at least said first clinical site for a purpose of developing a metric of clinical trial performance of said first site.

110-117. (canceled)

118. (withdrawn) A method according to claim 116, wherein said first and second clinical trial sub-protocol components are components of different clinical trial protocols.

119-136. (canceled)

137. (withdrawn) A method according to claim 128, wherein first and second ones of said sub-protocol components are components of first and second different clinical trial protocols.

138. (canceled)

139. (previously presented) A medium according to claim 1, wherein said post-enrollment workflow tasks include patient management tasks.

140. (previously presented) A medium according to claim 1, wherein said post-enrollment workflow tasks include the post-enrollment instruction to have a specified test performed on the patient.

REMARKS

The above Amendments and these Remarks are in reply to the final Office Action mailed 23 February 2007. No fee is due for the addition of any new claims. A request for a three-month extension of time is being electronically submitted herewith.

Claims 1-5, 8-11, 139 and 140 were pending in the Application prior to the outstanding Office Action. In the Office Action, the Examiner rejected all pending claims. The present Response makes no changes to the claims. Reconsideration of the rejections is requested.

I. REJECTION OF CLAIMS 1, 2, 4, 5, 8-11, 139 AND 140 UNDER 35 U.S.C. §103(a)

The Examiner rejected claims 1, 2, 4, 5, 8-11, 139 and 140 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Briegs U.S. Patent No. 7,054,823. The Examiner also rejected claim 3 under 35 U.S.C. §103(a) as being unpatentable over a combination of Colon, Briegs and Cimino.

Briegs, however, is not prior art, since its filing date did not precede the "date of the invention" by the inventors of the subject patent application. 35 U.S.C. §102(e).

Submitted herewith is a DECLARATION OF INVENTOR MICHAEL G. KAHN UNDER 37 C.F.R. §1.131(b), providing documentary evidence that the invention was conceived prior to September 10, 1999 (the filing date of the provisional application to which the Briegs patent claims priority), and that diligence toward reduction to practice existed from a date prior to September 10, 1999, until after Applicants' constructive reduction to practice date of May 31, 2000 (Applicants' filing date).

Also submitted herewith is a DECLARATION OF INVENTOR MICHAEL MISCHKE-REEDS UNDER 37 C.F.R. §1.131(b) to the same effect.

It can be seen that all of the elements of independent claim 1 were present in the system as conceived by the inventors and in the system being reduced to practice.

Accordingly, Briegs is not prior art and cannot, either by itself or in combination with any other reference, preclude patentability of Applicants' independent claim 1.

Claims 2-5, 8-11, 139 and 140 all depend ultimately from independent claim 1, and therefore should be patentable for at least the same reasons as claim 1. These claims also add their own limitations which, it is submitted, render them patentable in their own right. Applicants do not believe it necessary to address the substantive positions taken by the Examiner in

rejecting any of the claims, but state for the record that they continue to disagree with the Examiner's positions and do not acquiesce in them.

Accordingly, claims 1, 2, 4, 5, 8-11, 139 and 140 are believed to be patentable.

II. WHY THIS RESPONSE AND ACCOMPANYING DECLARATIONS SHOULD BE ENTERED

This Response (including the accompanying Declarations) should be entered under 37 CFR 1.116(b)(3) because the response is necessary and could not have been presented earlier. The response is necessary because it overcomes the Examiner's only ground for rejecting the claims. It could not have been presented earlier because the outstanding final Office Action was the first time that the Examiner cited Briegs, the reference which the Declarations submitted herewith antedates. Applicants could not have known the necessity to submit the Declarations at any time prior to the outstanding final Office Action.

Regardless of entry of the Response, the Declarations submitted herewith should be admitted under 37 CFR 1.116(e) for the same reason: They could not have been presented earlier. The outstanding final Office Action was the first time that the Examiner cited Briegs. Applicants could not have known the necessity to submit the Declarations at any time prior to the outstanding final Office Action. The Declarations are being submitted on the same date as the filing of an appeal.

III. OTHER MATTERS AND CONCLUSION

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The fee required for a three-month extension of time under 37 C.F.R. § 1.136 is being electronically submitted herewith, extending the time to respond up to and including August 23, 2007.

Also submitted herewith is a NOTICE OF APPEAL and the required fee.

Fee Authorization. The Commissioner is authorized to charge any additional fee(s) that may be required in connection with this Response, or to credit any overpayment, to Deposit Account No. 50-0869 (FSTK 1000-0).

Respectfully submitted,

Date: 23 August 2007 By: /Warren S. Wolfeld/
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